

## Back-Pocket Qs and As - Glyphosate

1. **What does EPA say about a recent verdict against Monsanto in which the jury found that Roundup was a factor in causing a groundskeeper's non-Hodgkin lymphoma? Does glyphosate cause non-Hodgkin lymphoma?**

The available scientific data do not support a cause-and-effect relationship between exposure to glyphosate and Parkinson's or non-Hodgkin's lymphoma, including the recently published analysis of the Agricultural Health Study (AHS) cohort.

2. **The International Agency on the Research for Cancer (IARC) concluded that glyphosate is "probably carcinogenic to humans." Does glyphosate cause cancer, and how is this information being considered?**

EPA scientists performed an independent evaluation of available data to determine the carcinogenic potential of glyphosate and concluded that glyphosate is "[ HYPERLINK "https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential" \l "a" ] to be carcinogenic to humans." For more information, read the [ HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073" ].

EPA's cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

IARC only considered a subset of the cancer studies included in EPA's evaluation. Additionally, IARC used studies that are not appropriate for determining human carcinogenic potential (e.g., genotoxicity studies in non-mammalian species that do not inform genotoxic risk in humans). EPA considered a significantly more extensive dataset, including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review.

3. **Why did California list glyphosate as a cancer agent under Proposition 65?**

One of the ways for a chemical to be added to the Proposition 65 list is if an "authoritative body" has identified it as an agent causing cancer. Given IARC's classification of the pesticides as "probably carcinogenic to humans," California has listed it as a substance under Proposition 65.

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Internal Background: As of July 2017, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) has listed glyphosate as an agent known to the state to

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cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Proposition 65 requires California to publish at least yearly a list of chemicals known to the state to cause cancer, birth defects, or reproductive toxicity.

**4. How is EPA responding to the EWG's petition in 2018 requesting that EPA lower its tolerance level for glyphosate on oats and prohibit preharvest use on oats? How will the petition affect EPA's evaluation of glyphosate?**

EPA is currently reviewing the petition and intends to address the petition as part of the ongoing registration review.

**5. Some countries in Europe and elsewhere have banned glyphosate. Why doesn't EPA?**

Countries such as El Salvador and the Netherlands have banned glyphosate, but they may operate under different environmental statutes and regulatory frameworks. U.S. law requires that EPA make decisions by first conducting a risk assessment. In addition, EPA must use the best science available in assessing potential risks from a pesticide prior to making a safety finding.

**6. Why has EPA raised the allowable level of glyphosate on oats over the years?**

This tolerance is harmonized with other international regulatory authorities and allows for trade with countries where glyphosate is used as a desiccant on oats (e.g., Canada). Currently, glyphosate is not registered in the United States for use as a desiccant on oats. There were no risks of concern identified in the current dietary risk assessment at the maximum allowable residue level on cereal grains. Oats belong to the cereal grains crop group (crop group 15). The current tolerance for cereal grains is 30 parts per million.

**7. Crops genetically engineered to tolerate being sprayed with glyphosate have led to a tremendous increase of glyphosate use. With growing use, is the pesticide being found more in food and water?**

Glyphosate use has increased over time since 1998, but the rate of increase has slowed over the last five years (according to market research data from 1998 to 2017). Recent monitoring studies have detected residues in food that are well below glyphosate tolerance levels. Glyphosate residues have been found in surface waters, but concentrations remain low and are not of concern. Given the historical lack of monitoring, it is unclear whether glyphosate residues in food and water have increased since the registration of genetically engineered crops. Despite low residue levels seen in monitoring data, there were no risks of concern identified in EPA's dietary assessment assuming maximum allowable levels.

**8. Who tests for GMO crops with residues of glyphosate?**

Food and food ingredients derived from genetically engineered plants are primarily regulated by the Food and Drug Administration (FDA) and must adhere to the same safety requirements that apply to food and food ingredients derived from traditionally bred plants. EPA is required by statute to evaluate all pesticides and ensure that there is a "reasonable certainty of no harm" to people when pesticides are applied according to the label, which includes application to genetically engineered plants.

EPA has determined that residues of glyphosate on any food/feed item (from genetically engineered plants or from traditionally bred plants) are safe for consumers provided the use complies with the existing labels.

**9. How can there be so many human incidents associated with glyphosate, and yet EPA finds no unreasonable human health risks from use of glyphosate?**

EPA routinely monitors a range of different data sources on human incidents, including EPA-mandated reporting under FIFRA section 6(a)(2), American Association of Poison Control Centers, and state-based surveillance programs. The number of reported glyphosate incidents is likely a result of glyphosate being among the most widely used pesticides by volume. However, it should be noted that, most of the incidents reported were minor in severity, meaning that symptoms resolved rapidly and usually involved skin, eye or respiratory irritation.

Most of the reported incidents were associated with accidents during application such as human error during application and container leaks of glyphosate products. In addition, more than 60% of all glyphosate incidents reviewed involved exposure to multiple pesticide ingredients or products and not glyphosate alone. Glyphosate products do not present risks when handled properly and in accordance with label directions. More information about the reported human health incidents is available in the glyphosate public docket.

**10. As part of ongoing litigation involving Bayer, it has also been reported that EPA employees (specifically Jess Rowland) colluded with Bayer to maintain that glyphosate does not cause cancer. What is EPA's response to these reports?**

When a chemical is under review, EPA maintains a dialogue with the pesticide registrants to obtain information needed for risk assessment or risk management. EPA also routinely meets with other interested stakeholders to discuss chemicals under review, including environmental groups and activist groups. Reports of alleged conversations between EPA officials and a chemical registrant taken out of context are not evidence of collusion. EPA employees maintain a high level of ethical conduct to maintain the public trust. There has never been any collusion and there currently is no collusion between EPA staff and representatives of Bayer.

**11. Recently, a collection of 20,000 documents from several sources, including EPA, were published online. The collection, with documents dating back to the 1920s, was termed the "Poison Papers." Environmental activists allege that the documents contain correspondence which show that Bayer doctored scientific studies in order for regulatory agencies to view glyphosate in a favorable light. What is EPA's response to this?**

EPA is aware of the so-called "Poison Papers." It appears to be a collection of records released through litigation. EPA has not reviewed all these documents and cannot comment on allegations of forgery by Bayer. EPA will continue to rely on the best scientific data available for its evaluation of glyphosate. The glyphosate dataset is composed of thousands of studies and consists of data from a variety of sources, including other pesticide companies, academia and published scientific literature. EPA's evaluation does not rely solely on data from Bayer or any other manufacturer. We look closely at every study to determine whether the results are scientifically sound. Our analysis gives greater weight to high-quality and well-documented studies and findings confirmed by multiple sources.

**12. Does EPA only use glyphosate studies submitted by pesticide companies to make its decisions?**

No, EPA considered information from all sources, including the open literature to conduct human health and ecological risk assessment for glyphosate.

The open literature review for human health risk assessment is described in the document [ [HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0067"](https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0067) ]. The open literature data evaluated for ecological risk assessment is described in the Agency's ecological risk assessment and also in [ [HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0078"](https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0078) ]. See [ [HYPERLINK "https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open"](https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open) ].

EPA requires a substantial amount of data to be collected and submitted for pesticide registration and registration review ([ [HYPERLINK "https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration"](https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration) ]). The required data include product chemistry, product performance, studies that determine hazard to humans and domestic animals, studies that determine hazard to non-target organisms, post-application exposure studies, applicator/user exposure studies, pesticide spray drift studies, environmental fate, and residue chemistry studies.

Although many of these studies are submitted by pesticide producers, EPA has [ [HYPERLINK "https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/master-list-test-guidelines-pesticides-and-toxic"](https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/master-list-test-guidelines-pesticides-and-toxic) ] for how studies must be conducted. The Agency independently evaluates required studies for scientific acceptability. Laboratories conducting studies must address Good Laboratory Practices (GLP) designed to ensure data quality and integrity. EPA's Office of Enforcement and Compliance Assurance (OECA) periodically inspects labs that conduct required studies to ensure that labs comply with GLP regulations.

When studies are submitted to the Agency for review, test reports must summarize and supply all the individual data obtained as part of the study. Our scientists prepare an independent evaluation for each study and generate a Data Evaluation Record (DER) to summarize the study methods, results and conclusions. DERs are subject to an internal peer review process and scientific review by committees within the Office of Pesticide Programs to ensure accuracy and consistency of interpretation prior to finalization.

**13. The human health risk assessment did not identify any human health risks from use of glyphosate, but the ecological risk assessment says there may be potential dietary risks for wild mammals. Since humans are mammals, why the discrepancy?**

Conclusions of potential dietary risk can differ between wild mammals and humans for a number of reasons, such as the assumptions used to model dietary exposure. The ecological risk assessment assumes that wild mammals can eat freshly sprayed foliage in the field, while the human health risk assessment considers consumption sometime after treatment, harvest, and/or processing. For ecological risk assessments, the Agency may assume that the entire diet of a wild mammal may be composed of just one food item (*e.g.*, seeds) that is treated with a pesticide, while the human health risk assessment considers the more varied consumption patterns of humans (*e.g.*, different fruits, grains or vegetables). EPA's assessments also account for wild mammals eating food elements (such as grasses or the outer layers of food items) that humans do not. The ecological risk assessment also considers wild mammals with smaller body sizes than what is assumed for humans. Together, these differences lead to different exposure assumptions and therefore different risk estimates.

## Use/Benefits:

### **14. How much glyphosate is used in the United States each year?**

Glyphosate is one of the most widely used herbicides in the United States. Approximately 290 million pounds of glyphosate are applied annually in agricultural crop production. Most glyphosate is applied on glyphosate-resistant corn and glyphosate-resistant soybeans. Approximately 24 million pounds are applied to non-agricultural areas annually. Glyphosate makes up 40 percent of the total pounds of herbicides sold in the U.S. for residential use (where approximately 5 million pounds are applied annually).

### **15. Are there alternatives to glyphosate?**

The Agency has determined that no single alternative herbicide exists for glyphosate with the same range of uses and range of application methods. Alternative herbicides can be identified for high acreage crops such as corn and soybean, but these alternatives may be more toxic than glyphosate.

Glyphosate targets a broad range of weeds and confers benefits for growers and land managers in both agricultural and non-agricultural settings. It is important in the production of glyphosate-resistant field crops such as corn, soybean, cotton and sugar beet. It is also important in the production of fruits, vegetables and nuts. It is the leading herbicide for the management of invasive and noxious weeds and is used to manage pastures, rangeland, rights of ways, forests, public land, and residential areas. In addition, glyphosate has low residual soil toxicity and helps retain no-till and low-till farming operations.

## Other Human Health

### **16. Does glyphosate cause celiac and digestive problems?**

The existing scientific data do not indicate any adverse impact on the gut microbiome (colonies of microbes in the gut). Although gut microbiomes are not evaluated directly in guideline studies, the stomach and gastrointestinal tract are examined in several studies by gross evaluation and histopathological investigations. There are no indications in these studies that exposure to glyphosate induces gross or histopathological effects on the stomach or gastrointestinal tract.

### **17. Is glyphosate present in vaccines?**

EPA has reviewed reports from various groups that claim that glyphosate residues have been found in vaccines; however, EPA identified several methodological issues (*e.g.*, collection procedure, analytical methods) with these analyses, which raise questions about the validity of these findings. To date, EPA is not aware of any peer-reviewed, scientifically valid data which demonstrates the presence of glyphosate in vaccines.

### **18. There are reports that glyphosate was recently detected in Ben & Jerry's ice cream, honey, beer, wine, cereal, and other food/beverage commodities. Why is glyphosate so prevalent in common foods? Given that some of these reports include food/drink that children regularly consume, should parents be especially concerned?**

Before allowing the use of a pesticide on food crops, EPA sets a maximum legal residue limit (called a tolerance) for each treated food. The tolerance is the residue level that triggers enforcement action. That is, if residues are found above that level, the commodity will be subject to seizure by the government. The presence of a detectable pesticide residue does not mean the residue is at an unsafe level.

Due to its widespread use, trace amounts of glyphosate residues may be found in various food and beverage commodities. However, these trace amounts are not of concern for the consumer. As part of the human health risk assessment, EPA evaluated all populations, including infants, children and women of child-bearing age. There were no dietary risks of concern for glyphosate using an unrefined analysis, which assumes all food commodities contain tolerance level residues (*i.e.*, maximum legal residues allowed on a food commodity) of glyphosate, all food has been treated with glyphosate, and using high-end estimates of glyphosate in drinking water.

#### **19. Should I be concerned about glyphosate on fresh fruits, vegetables, cereals and other foods?**

No. EPA sets limits on how much pesticide residue can remain on food and feed products, or commodities. Pesticide residue limits are known as [ [HYPERLINK "http://www2.epa.gov/pesticide-tolerances/about-pesticide-tolerances"](http://www2.epa.gov/pesticide-tolerances/about-pesticide-tolerances) ], or maximum residue levels. The tolerance is the residue level that triggers enforcement action; the Food and Drug Administration (FDA) is the agency responsible for enforcing tolerances. If residues are found above the tolerance level in a food, the commodity will be subject to seizure by the FDA. The complete listing of tolerances for glyphosate can be found in [ [HYPERLINK "https://www.gpo.gov/fdsys/granule/CFR-2010-title40-vol23/CFR-2010-title40-vol23-sec180-364"](https://www.gpo.gov/fdsys/granule/CFR-2010-title40-vol23/CFR-2010-title40-vol23-sec180-364) ].

EPA conducted a highly conservative dietary risk assessment for glyphosate that assumed that 100% of registered crops were treated with glyphosate, that residues on food/feed items were at the tolerance level for each crop, and that residues in drinking water were from direct application of glyphosate to water. These assumptions would lead to much higher estimated levels of exposure than would be expected to occur with actual use. The resulting conservative estimates of dietary exposures were not of concern. Therefore, residues of glyphosate in food/feed commodities and drinking water are not of concern for adults and children.

#### **20. Is glyphosate present in human milk, tissues and urine?**

At this time, EPA is not aware of any scientifically valid, peer-reviewed study reporting glyphosate residues being detected in human milk or tissue. Some groups have claimed to detect glyphosate in breast milk; however, the Agency has found several issues with the studies making these claims. Such studies are missing key information related to sampling methods, sample storage, sample shipping, quality assurance/quality control, and analytical methods used.

Based on the available data, glyphosate has little potential to bioaccumulate in human tissue and breast milk. To further examine whether glyphosate can be found in human breast milk, EPA conducted an [ [HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0085"](https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0085) ]. Using highly sophisticated analytical sampling procedures that can detect glyphosate and/or its metabolites at extremely low doses, neither glyphosate nor its metabolites detected in breast milk.

Detection of trace amounts of glyphosate in urine would be expected, given that glyphosate does not bioaccumulate and is primarily excreted un-metabolized by humans. Such trace levels in urine are not of concern for consumers.

## **21. Are children more sensitive to glyphosate than adults?**

EPA places top priority on the safety of children near areas treated with pesticides. After evaluating numerous studies from a variety of sources, the Agency found no indication that children are more sensitive to glyphosate from *in utero* or post-natal exposure. As part of the human health risk assessment, the Agency evaluated all populations, including infants, children, and women of child-bearing age, and found no risks of concern from ingesting food with glyphosate residues assuming that all food included in the dietary risk assessment have been treated with glyphosate (i.e., 100% crop treated) and contain tolerance level (maximum legal level) residues. EPA also found no risks of concern for children entering or playing on residential areas treated with glyphosate. Aggregate exposures or combined risk from children playing on treated areas, eating, and drinking water with glyphosate residues also resulted in no risks of concern.

## **22. Is glyphosate an endocrine disruptor?**

Glyphosate has undergone [ [HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0047"](https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0047) ] under EPA's [ [HYPERLINK "https://www.epa.gov/endocrine-disruption"](https://www.epa.gov/endocrine-disruption) ]. Based on all available information, EPA concluded, using a weight-of-evidence approach, that the existing data do not indicate that glyphosate has the potential to interact with the estrogen, androgen or thyroid signaling pathways. The screening program did not indicate the need for additional testing for glyphosate.

### **Other Ecological:**

## **23. Glyphosate kills milkweed, a key resource for the monarch butterfly. What is EPA doing to protect the monarch butterfly?**

Glyphosate is an herbicide registered for use on milkweed, which is considered a weed in agricultural settings. Milkweed is poisonous to livestock. Glyphosate, like all similar herbicides, may indirectly affect the monarch butterfly by affecting milkweed and other nectar sources. However, it is not known to what extent glyphosate, or herbicide use in general, may contribute to the decline of the monarch butterfly.

Threats to the monarch butterfly population are multi-pronged and include loss of breeding habitat, loss of overwintering habitat in Mexico, changes in weather patterns, and other factors. EPA believes that a holistic approach is needed for monarch conservation that considers herbicides in general, not just glyphosate, as well as other factors that may play a role in the monarch decline. EPA also believes it is important to balance weed management needs with monarch conservation needs.

EPA is taking steps to protect the monarch butterfly and other pollinators through registration, registration review, and other stakeholder outreach activities. EPA is focused on label language; cooperative efforts with federal, state, and other stakeholders; outreach and communication; promoting best management and integrated pest management practices; and science and risk assessment. Read more about what EPA is doing to protect the monarch butterfly. [[hyperlink to monarch page](#)].

## **24. How does glyphosate affect endangered species?**

EPA's ecological risk assessment does not currently include a complete national-level assessment of risks to endangered species. EPA is scheduled to complete an endangered species effects determination for glyphosate by June 2020. If EPA determines that glyphosate may affect listed species, we will initiate consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together known as "the Services"). The Agency is currently working with its federal partners, including USDA and the Services, to determine a risk assessment approach for endangered species. Find more information about the [ [HYPERLINK "http://www2.epa.gov/endangered-species/about-endangered-species-protection-program."](http://www2.epa.gov/endangered-species/about-endangered-species-protection-program) ].

## **25. What happens to glyphosate in the environment?**

Glyphosate is degraded by bacteria in the soil and aquatic environments. The half-life in soil ranges from 2 days to 142 days, depending on the environmental conditions. In aquatic environments, glyphosate is more persistent. The major degradation products of glyphosate are aminomethylphosphonic acid (AMPA) and carbon dioxide. Glyphosate binds to soil, which limits leaching and runoff from application sites; however, glyphosate can move to surface water by spray drift and soil erosion.

## **26. Is glyphosate a metal chelator? What does that mean for humans or for the environment?**

Glyphosate chelates, or bonds, with some metals in soil and aquatic environments. The relative proportion of the various chemical species of glyphosate (including dissociated species of glyphosate acid and glyphosate-metal complexes) is dependent on chemical characteristics (*e.g.*, pH, redox potential, etc.) of the environment. Although glyphosate-metal chelation has been associated with micronutrient deficiencies for crop plants, EPA is unaware of any connection between metal chelation and ecotoxicity of glyphosate. In guideline studies for human health, exposure to glyphosate did not result in any changes in clinical or blood chemistry measurements, suggesting that chelation does not play a significant role in affecting human health.